

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 32-R-0003  
CUSTOMER NUMBER: 770

FORM APPROVED  
OMB NO. 0579-0036

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**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

Eli Lilly And Company  
Lilly Corporate Center  
Indianapolis, IN 46285

Telephone: (317) -276-2000

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	4	7	780	35	822
5. Cats	3	0	15	0	15
6. Guinea Pigs	0	47	208	0	255
7. Hamsters	0	10	159	0	159
8. Rabbits	0	690	156	2	848
9. Non-human Primates	1	1	317	2	320
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferret	0	2	68	1	71
Gerbil	0	0	377	0	377

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

(b)(6), (b)(7)c

DATE SIGNED  
26 Nov  
2007

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# ATTACHMENT TO ANNUAL REPORT OF RESEARCH FACILITY

For the period of October 1, 2006 through September 30, 2007

## Category "E" Experimentation

**Eli Lilly and Company  
Indianapolis, IN 46285**

**Registration No. 32-R-0003  
Customer No. 770**

Animals upon which experiments, research, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

Species	Number of Animals	Explanation
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<u>Dogs</u>	1	Toxicology
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This animal was used in the toxicological evaluation of different formulations to determine if cardiotoxicity could be reduced. One animal was euthanized. Lower species could not be used. Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies may experience unanticipated events.

<u>Dogs</u>	20	Pharmacology
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These animals were used as a model to evaluate new compounds for osteoarthritis in humans and companion animals. When adverse clinical signs were detected, animals were provided veterinary and supportive care. Animals were euthanized when it was determined that pain or distress could not be alleviated. In vitro work and work with lower species was done prior to the use of this species.

<u>Dogs</u>	14	Toxicology
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These animals were used in the toxicological evaluation of drug candidates, novel pharmaceuticals. In some studies, the degree of toxicity was unexpectedly severe. When adverse clinical signs were detected, animals were provided veterinary and supportive care. Animals were euthanized when it was determined that pain or distress could not be alleviated. Administration of analgesics or tranquilizers would have confounded interpretation of the experimental results. Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies used in the evaluation of new drug candidates may experience unanticipated events. U.S. and O.U.S. regulations and guidelines for animal studies to support human clinical trials, specifically 21 CFR 312.23 (a)(8)(ii) and ICH SF4, require these studies.

<u>Ferret</u>	1	Toxicology
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This animal was used in the toxicological evaluation of different formulations to determine if cardiotoxicity could be reduced. When adverse clinical signs were detected, the animal was provided veterinary and supportive care, but was euthanized. Lower species could not be used.

Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies may experience unanticipated events.

Rabbits                      2                      Toxicology

These animals were used in the toxicological evaluation of drug candidates. In some studies, the degree of toxicity was unexpectedly severe. When adverse clinical signs were detected, animals were provided veterinary and supportive care. Animals were euthanized when it was determined that pain or distress could not be alleviated. Administration of analgesics or tranquilizers would have confounded interpretation of the experimental results, and the animal was euthanized. Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies used in the evaluation of new drug candidates may experience unanticipated events. U.S. and O.U.S. regulations and guidelines for animal studies to support human clinical trials, specifically 21 CFR 312.23 (a)(8)(ii) and ICH SF4, require these studies.

Monkeys                      2                      Toxicology

These animals were used in the toxicological evaluation of drug candidates. In some studies, the degree of toxicity was unexpectedly severe. Animals received veterinary care but either died spontaneously or were euthanized. Administration of analgesics or tranquilizers would have confounded interpretation of the experimental results. Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies used in the evaluation of new drug candidates may experience unanticipated events. U.S. and O.U.S. regulations and guidelines for animal studies to support human clinical trials, specifically 21 CFR 312.23 (a)(8)(ii) and ICH SF4, require these studies.

## **ATTACHMENT TO ANNUAL REPORT OF RESEARCH FACILITY**

For the period of October 1, 2005 through September 30, 2006

### **Exceptions to the Regulations and Standards**

**Eli Lilly and Company  
Indianapolis, IN 46285**

**Registration No. 32-R-0003  
Customer No. 770**

**1. Identify the IACUC approved exception to the standards**

1. Use of a 24 hour light cycle
2. Multiple major surgery

**2. Describe the IACUC approved exception to the standards**

1. The IACUC approved the use of a 24 hour light cycle in one protocol for no more than twice a week for two weeks total for pharmacology studies.
2. In one protocol the IACUC approved two major surgeries in a canine renal model because published literature and specific expertise on the model indicated greater survival rates and viability with two rather than one surgery.

**3. Species of animal used**

1. Dog
2. Dog

**4. Number of animals used**

1. None- protocol not used
2. Twenty two dogs experienced two major surgeries

# **ATTACHMENT TO ANNUAL REPORT OF RESEARCH FACILITY**

For the period of October 1, 2006 through September 30, 2007

## **Sites and Locations and Listing**

**Eli Lilly and Company  
Indianapolis, IN 46285**

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This institution has been designated by the Agency as a single "site". The animal care and use facilities within this site designation are in multiple buildings in two locations.

- Eli Lilly and Company, Lilly Corporate Center, Indianapolis, Indiana, 46285.

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Any requests for information or access to the site should be made through the Corporate Center location.